K120721

APR - 6 2012

510(k) SUMMARY

EOS imaging's EOS

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

EOS imaging
10 rue Mercoeur
PARIS F-75011
FRANCE

Phone: + 33 1 55 25 60 60
Facsimile: + 33 1 55 25 60 61

Contact Person: Karine Chevrie, Quality and Regulatory Affairs Officer

Date Prepared: April 4, 2012

Name of Device and Name/Address of Sponsor:

EOS
EOS imaging
10 rue Mercoeur
PARIS F-75011
FRANCE

Common or Usual Name: Digital Radiography System

Classification Name: Radiology

Predicate Devices: EOS imaging's EOS (K071546)

Purpose of the Special 510(k) notice.

The modified EOS is a modification to the cleared EOS.

Intended Use

The EOS is intended for use in general radiographic examinations and applications, excluding the evaluation of lung nodules and examinations involving fluoroscopy, angiography and mammography. EOS allows the radiographic acquisition of either one or two orthogonal X ray images for diagnostic purposes, in one single scan, of the whole body or a reduced area of investigation of a patient in the upright or seated position.

Technological Characteristics

EOS is a digital radiography system in which two sets of xenon gas filled digital detectors and X-ray tubes are positioned orthogonally to generate frontal and lateral images simultaneously by scanning the patient over the area of interest. The diagnostic images are stored in a local database and are displayed on a high-resolution, medical-quality monitor, where the diagnosis is performed. The diagnostic image can be transmitted through a DICOM 3.0 compatible digital network for printing and archiving. The fundamental technological characteristics of the modified EOS are unchanged compared to the cleared EOS.

Performance Data

EOS is designed to conform with IEC 60601-1 and collateral standards. An IECEE CB (certification body) test certificate has been issued. Additional performance and functional testing has confirmed the equivalent performance of the modified EOS compared to the EOS. This testing included bench testing to confirm equivalent resolution and accuracy of the modified EOS, and mechanical resistance testing of the stabilization accessory. Software verification and validation testing was also conducted.

Substantial Equivalence

The modified EOS has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared EOS. The minor differences in the modified EOS's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified EOS is as safe and effective as the cleared EOS. Thus, the modified EOS is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

APR - 6 2012

EOS Imaging
% Mr. John Smith
Regulatory Counsel
Hogan Lovells US L.L.P.
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K120721
Trade/Device Name: EOS
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 8, 2011
Received: March 8, 2011

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: EOS

Indications for Use:

The EOS is intended for use in general radiographic examinations and applications, excluding the evaluation of lung nodules and examinations involving fluoroscopy, angiography and mammography. EOS allows the radiographic acquisition of either one or two orthogonal X ray images for diagnostic purposes, in one single scan, of the whole body or a reduced area of investigation of a patient in the upright or seated position.

Prescription Use __x___ (Per 21 C.F.R. 801.109)	AND/OR	Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120721